IN THE UNITED STATES DISTRICT COURT
FOR SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SHAMROCK MEDICAL SOLUTIONS GROUP, LLC, a limited liability company, and JOHN P. REICHARD, ROBERT E. TROOP, DAVID L. BYSTROM, and REBECCA H. MULLIS, individuals, Defendants.	)	Civil No. 2:13-cv-590

COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents that:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Shamrock Medical Solutions Group ("Shamrock"), a limited liability company, and John P. Reichard, Robert E. Troop, David L. Bystrom, and Rebecca H. Mullis, individuals (collectively "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(a) and (j); and (b) violating 21 U.S.C. § 331(k) by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) and misbranded within the meaning of 21 U.S.C. §§ 352(a) and (j) while they are held for sale after shipment in interstate commerce.

Jurisdiction and Venue

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

Defendants

4. Shamrock Medical Solutions Group, LLC ("Shamrock"), is an Ohio limited liability company that repackages, labels, and holds drugs in solid and liquid oral dosage form and distributes them to hospitals pharmacies. Shamrock is currently located at 741 Radio Drive, Lewis Center, Ohio (the "Lewis Center facility"), within the jurisdiction of this Court. Prior to 2011, Shamrock also conducted business at 250 Revolutionary Drive, Suite 200, East Taunton, Massachusetts (the "East Taunton facility"). The same senior management and corporate policies that govern the Lewis Center facility governed the East Taunton facility.

5. John P. Reichard is the President and Chief Operating Officer of Shamrock. He has responsibility over all of Shamrock's operations including but not limited to the packing, labeling, holding, and distribution of drugs. He has the authority to institute company procedures, including procedures related to quality control. He had similar authority over the East Taunton facility. Reichard performs his duties at the Lewis Center facility, within the jurisdiction of this Court.

6. Robert E. Troop is Shamrock's Chief Executive Officer and Chairman of the Board of Directors. He provides leadership and strategic direction for Shamrock. He had similar authority over the East Taunton facility. Troop performs his duties related to Shamrock in Westlake, Ohio.

7. David L. Bystrom is the Director of Quality Assurance for Shamrock. He is responsible for conducting packing, labeling, and expiration dating inspections. He performs his operations at the Lewis Center facility, within the jurisdiction of this Court.

8. Rebecca H. Mullis is the Manager of Operations for Shamrock. She is responsible for reviewing Master Production and Control Records, Batch Production and Control Records, and Standard Operating Procedures. She performs her duties at the Lewis Center facility, within the jurisdiction of this Court.

9. The articles that Defendants repackage, label, hold, and distribute to hospital pharmacies are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and/or "intended to affect the structure or any function of the body" and are therefore drugs under the Act, 21 U.S.C. §§ 321(g)(1)(B) & (C).

10. Defendants repackage, label, and hold drug products that have been shipped to them in interstate commerce from locations outside Ohio, including West Virginia, and distribute their repackaged drug products in interstate commerce to hospital pharmacies throughout the country, including Massachusetts.

Adulterated Drugs

11. A drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("cGMP") to assure that such drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B). The cGMP regulations, 21 C.F.R. Parts 210 and 211, establish the minimum cGMP requirements applicable to human drugs and require manufacturers to control

all aspects of the processes and procedures by which drugs are manufactured, to prevent the production of unsafe, ineffective, and improperly labeled products.

12. Five comprehensive FDA inspections of Defendants' facilities since 2007 have established that the methods, facilities, and controls Defendants use for repackaging, labeling, and holding drugs do not conform to cGMP requirements and, therefore, Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

13. FDA inspected Defendants' Lewis Center facility most recently between February 5 and March 5, 2013. That inspection documented serious, pervasive cGMP deficiencies, including:

A. Failure to establish adequate written procedures designed to assure that Defendants' drug products have the identity, strength, quality, and purity that they purport or are represented to possess and failure of the quality control unit to follow such procedures and, if inadequate, reject such procedures, in violation of 21 C.F.R. §§ 211.100(a), 211.22(c) and (d). Some of Defendants' procedures are inadequate because they fail to address all potential risk in the work flow process. Additionally, Defendants' quality control unit did not consistently follow the firm's procedures. For instance, on three separate occasions, Defendants' quality control unit approved for distribution drugs with incorrect labels contrary to Defendants' own procedures (*e.g.*, Defendants approved Oxycodone HCl labeled as Morphine Sulfate; Docusate Calcium labeled as Docusate Sodium; and Metformin Extended Release labeled as Metformin Immediate Release);

B. Failure to collect and visually examine for correct labeling a representative sample of units at the completion of finishing operations, in violation of 21 C.F.R. § 211.134(b). Defendants' procedures require that a quality unit employee collect and visually examine only

the last unit dose in any given lot; however, because repackaging operations are sometimes interrupted, the last unit dose in a given lot is not always an adequate representative sample. As a direct result of this procedure, Defendants distributed misbranded drugs on three occasions (*e.g.*, Defendants distributed Sulfamethoxazole and Trimethoprim 800/160mg labeled as Sulfamethoxazole and Trimethorpim 400/80mg; Pramipexole labeled as Nebivolol; and Diltiazem labeled as Thiamine);

C. Failure of batch production and control records to include complete information relating to the production and control of each batch, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, in violation of 21 C.F.R. § 211.188(b). For instance, Defendants' procedures do not require batch record documentation of unusual events that occur during repackaging operations; and

D. Failure to thoroughly investigate any unexplained discrepancy and failure of a batch or any of its components to meet any of its specifications, regardless of whether the batch had already been distributed, in violation of 21 C.F.R. § 211.192. For instance, FDA investigators observed ten examples where Defendants did not complete an investigation for a high yield variance (Defendants distributed more containers of finished product than anticipated, meaning the containers were under filled) and three examples where Defendants did not complete an investigation for a low yield variance (Defendants distributed fewer containers of finished product than anticipated, meaning the containers were over filled).

14. FDA's inspections of the Lewis Center facility conducted between August 3 and 24, 2011, and November 2007, documented many of the same and/or similar pervasive cGMP deficiencies with respect to Defendants' methods, facilities, and controls used for repackaging,

labeling, and holding drugs, including, but not limited to, Defendants' inadequate procedures for production and process controls designed to ensure that Defendants' drugs have the identity, strength, quality, and purity that they purport to or are represented to possess (in violation of 21 C.F.R. § 211.100(a)); inadequate documentation of complaint investigations (in violation of 21 C.F.R. § 211.198(b)(2)); inadequate controls over computer systems to ensure that changes made to the Master Production and Control Record are made only by authorized personnel (in violation of 21 C.F.R. § 211.68(b)); inadequate quality control (in violation of 21 C.F.R. § 211.22(d)); failure to establish and follow written procedures to assure batch uniformity and integrity of drugs (in violation of 21 C.F.R. § 211.110(a)); and incomplete batch production and control records (in violation of 21 C.F.R. § 211.188).

15. FDA's inspection of Defendants' East Taunton facility between January – February 2011, and July – August 2009, documented many of the same and/or similar cGMP violations, including, but not limited to, Defendants' inadequate investigation of unexplained discrepancies (in violation of 21 C.F.R. § 211.192); failure to clean equipment and utensils to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug (in violation of 21 C.F.R. § 122.67(a)); and failure to exercise strict control over the issuance of labeling (in violation of 21 C.F.R. § 211.125).

16. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

17. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated, within the meaning of 21 U.S.C. § 351(a)(2)(B), after shipment in interstate commerce, as set forth above.

Misbranded Drugs

18. As described in paragraphs 13-17, Defendants have repeatedly distributed mislabeled drug products that incorrectly identify the drug, strength and/or dosage form.

19. Because the labeling of such drugs is false, the drugs are misbranded under 21 U.S.C. § 352(a).

20. Defendants' mislabeled drug products are also misbranded under 21 U.S.C. § 352(j) in that the products are "dangerous to health when used in the dosage or manner . . . frequency or duration prescribed, recommended, or suggested in the labeling . . . ." For example, as discussed in paragraph 13(A), Defendants distributed to hospital pharmacies oxycodone HCL oral concentrate incorrectly labeled as morphine sulfate oral solution. Oxycodone is approximately 1.5 times more potent than morphine.

21. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. §§ 352(a) and (j), as set forth above.

22. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become misbranded, within the meaning of 21 U.S.C. §§ 352(a) and (j), after shipment in interstate commerce, as set forth above.

History

23. Defendants' noncompliance has continued despite repeated warnings from FDA regarding their cGMP and labeling violations.

24. At the conclusion of each FDA inspection, the FDA investigator(s) issued a detailed List of Inspectional Observations (Form FDA 483) to Shamrock's management and discussed

the inspectional findings with them. The Forms FDA 483 issued at the conclusion of the 2013 and both 2011 inspections were issued to Defendant Reichard.

25. FDA sent a Warning Letter to Shamrock on April 8, 2010, which detailed cGMP deficiencies observed during FDA's 2009 inspections of Defendants' East Taunton facility. The Warning Letter also informed Shamrock that some of its products were misbranded under 21 U.S.C. § 352(f)(1). The Warning Letter emphasized the serious nature of the violations and stated that a failure to correct the violations could lead to regulatory action including an injunction.

26. On March 10, 2011, FDA held a Regulatory Meeting with Defendants Reichard and Troop to discuss Defendants' persistent cGMP violations at their East Taunton facility, to better understand the corrective actions Defendants intended to implement, and to explain to Defendants the severity of the situation. FDA informed Defendants that their written response on February 25, 2011, was inadequate to show sufficient progress had been made since FDA's February 2011 inspection, expressed concern that Defendants' cGMP deficiencies could result in drugs being mislabeled, and reiterated that the agency could pursue seizure or injunction if improvements were not made.

27. On June 15, 2012, FDA issued a second Warning Letter to Shamrock, addressed to Defendant Reichard. The 2012 Warning Letter detailed the cGMP deficiencies observed at Defendants' Lewis Center facility during the 2011 Lewis Center facility inspection. The violations noted in the Warning Letter were similar to those observed during prior Lewis Center facility inspections and East Taunton facility inspections. The Warning Letter also informed Shamrock that some of their drug products were misbranded under 21 U.S.C. § 352(b)(2). The Warning Letter once again emphasized the serious nature of the cGMP and labeling violations at

the Lewis Center facility and stated that a failure to correct the violations could lead to regulatory action including an injunction.

28. Defendants responded in writing to the Forms FDA 483 from all five inspections, to the Warning Letters, and to the Regulatory Meeting. In their responses, Defendants attempted to justify their failure to follow their own procedures, promised improvements, and/or submitted information purporting to show that corrective actions had been taken. Yet, as FDA investigators repeatedly documented during each of the subsequent inspections, Defendants' promises have not been kept, and their attempts to remedy their cGMP and labeling deficiencies have been wholly inadequate.

29. Defendants' conduct demonstrates their refusal to comply with the law. Unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a) and (k), in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants Shamrock Medical Solutions Group, LLC, John P. Reichard, Robert E. Troop, David L. Bystrom, and Rebecca H. Mullis, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs to become adulterated, within the meaning of 21 U.S.C. § 351(a)(2)(B), while the drugs are held for sale after shipment in interstate commerce;

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a) and (j); and

D. Violating 21 U.S.C. § 331(k) by causing drugs to become misbranded, within the meaning of 21 U.S.C. §§ 352(a) and (j), while the drugs are held for sale after shipment in interstate commerce;

II. Permanently restrain and enjoin Defendants Shamrock Medical Solutions Group, LLC, John P. Reichard, Robert E. Troop, David L. Bystrom, and Rebecca H. Mullis, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with cGMP requirements and the Act, in a manner that has been found acceptable by FDA;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

DATED this 20th day of June, 2013.

Respectfully submitted,

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